K00 2916

NOV 2 8 2000

510(k) Summary

Surgi-Vision Prostate Coil

Common/Classification Name: Accessory to
Magnetic Resonance Diagnostic Device, 21 CFR 892.1000

Surgi-Vision, Inc.
9250 Rumsey Road, Suite 100
Columbia, MD 21045

Contact: Nancy E. Taylor, Prepared: September 18, 2000

A. LEGALLY MARKETED PREDICATE DEVICES

The **Surgi-Vision Prostate Coil** is substantially equivalent to the Medrad MRInnervu Endorectal MRI Coils, which were cleared for marketing on June 26, 1995, in premarket notifications K952232 and K952235.

B. DEVICE DESCRIPTION

The **Surgi-Vision Prostate Coil** is a specialty coil for use in MRI imaging of the anatomical regions surrounding the urethra. The signals picked up by the coil are conducted through a small coaxial cable to a connection with the standard surface coil connector for GE MRI systems. The coil and cable are completely sealed inside the insulating layer.

C. INTENDED USE

The Surgi-Vision Prostate Coil is recommended for high-resolution Magnetic Resonance Imaging of the male prostate and surrounding tissue. The single use, disposable coil was designed to be inserted in the urethra of the patient during MRI scans in order to obtain improved image quality in the anatomical regions surrounding the urethra including the prostate. The flexible coil facilitates placement of the coil in the anatomy. This product is to be used with a 1.5T GE Signa MRI machine.

K002916

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Surgi-Vision Prostate Coil** has similar but not identical indications for use as the legally marketed predicate device. However, the intended use, providing intercavitary reception of MRI signals for the purpose of creating an MRI image of nearby anatomy, is the same.

The **Surgi-Vision Prostate Coil** has the same technological characteristics as the predicate device. Both proposed and predicate devices have an electronic matching circuit, a connecting coaxial cable, and an intercavitary probe with a radiofrequency receiving coil. However, there are differences in construction and design that make it necessary to provide performance data to assure substantial equivalence. Such performance data are available and do demonstrate substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

See Section D, above.

F. TESTING

Surgi-Vision carried out testing and/or analysis of the **Surgi-Vision Prostate Coil** that addressed the following issues:

(1) Possibility of excess RF heating;

(2) Possibility of increased susceptibility of patients to peripheral nerve stimulation;

(3) Imaging performance; and

(4) Mechanical testing.

The results of the heating experiments demonstrate that there is no excess heating when SVPC is positioned in a phantom that is representative of clinical conditions. The SAR observed during use of the SVPC does not exceed the limits defined for MRI safety in EN 60601-2-33.

K002916

The calculations done to determine current leakage by the MRI pulsed gradient field demonstrate that there is no possibility of increased susceptibility of patients to nerve stimulation.
The imaging performance was evaluated in a canine model as shown in Exhibit VI. The canine model was selected for its similarity of cutaneous and subcutaneous tissue structure. Comparison images were done using a body coil. The SVPC images demonstrate enhanced resolution of the prostate as compared to the body coil images taken with the same imaging parameters.

Mechanical tests demonstrated tensile results that exceeded the one pound minimum. Mechanical flexing resulted in insignificant changes in the electrical properties of the coils. These results are described in Exhibit XI.

The results of the testing demonstrate that there are no safety problems for imaging of a patient using the **Surgi-Vision Prostate Coil** if the instructions for use are followed.

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2000

Nancy Taylor
CEO/President
Surgi-Vision, Inc.
9250 Rumsey Rd., Suite 100
Columbia, MD 21045

Re: K002916
Surgi-Vision Prostate Coil
Dated: September 18, 2000
Received: September 19, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K002916

Device name: Surgi-Vision Prostate Coil

Indications for Use:

The Surgi-Vision Prostate Coil is recommended for high-resolution Magnetic Resonance Imaging of the male prostate and surrounding tissue. The single use, disposable coil was designed to be inserted in the urethra of the patient during MRI scans in order to obtain improved image quality in the anatomical regions surrounding the urethra including the prostate. The flexible coil facilitates placement of the coil in the anatomy. This product is to be used with a 1.5T GE Signa MRI machine.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

David A. Seguin
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002916